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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/024,513	12/21/2001	Juan Mantelle	041457-0630	4098

22428 7590 12/15/2003

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WASHINGTON, DC 20007

EXAMINER

CHOI, FRANK I

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 12/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/024,513

Applicant(s)

MANTELLE ET AL.

Examiner

Frank I Choi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,7-14,16-23,25-32 and 34-38 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

- 5) ☐ Claim(s) _____ is/are allowed.

- 6) ☒ Claim(s) 1-5,7-14,16-23,25-32 and 34-38 is/are rejected.

- 7) ☐ Claim(s) _____ is/are objected to.

- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Specification

The amendment filed 9/25/2003 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: correction of "5,676,386" to "5,656,286". Applicant offers no explanation as to the change in patent number. The original disclosure contained the former patent number, as such, the change to a different patent number appears to constitute new matter.

Applicant is required to cancel the new matter or provide sufficient explanation as to the basis and support for the above-mentioned amendment in the reply to this Office Action.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 7-9 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over WO 01/10420.

WO 01/10420 expressly discloses a patch which contains methylphenidate which delivers at a rate falling within the scope of the claims wherein there is no degradation of methylphenidate (Pg. 5, 1st paragraph, Pgs. 18, 19, Examples 4, 5, Figures 3, 4).

Alternatively, at the very least the claimed invention is rendered obvious within the meaning of 35 USC 103, because the prior art discloses products and uses that contain the same exact ingredients/components as that of the claimed invention. See *In re Fitzgerald*, 205 USPQ 594 (CCPA 1980). See also *In re May*, 197 USPQ 601, 607 (CCPA 1978).

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

Applicant argues that Vickers does not disclose a composition that comprises no more than about 5 weight % of acid functional monomers. In the first instance, Applicant does not indicate the scope of the limitation "about". In the second instance, Applicant has not shown that the prior art composition does not comprise no more than about 5 weight % of acid functional monomers, i.e. Applicant must show that the adhesive in Example 1 (Vickers, Pgs. 15, 16) does not comprises no more than about 5 weight % of acid functional monomers. The arguments of counsel cannot take the place of evidence in the record. In *re Schulze*, 145 USPQ 716, 718 (CCPA 1965). With respect to the obviousness arguments, Examiner notes that in an inherency-based 102/103 rejection, the *Graham v. John Deere* factors are not applicable, as such, the issue as to what Vickers would have suggested is not at issue.

Claims 1-5, 7-14, 16-23, 25-32, 34-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 01/10420 in view of *Miranda et al.* (US Pat. 5,656,286).

WO 01/10420 discloses a patch which contains methylphenidate which delivers the majority of the methylphenidate over the desired period, such as 12 hours, after which plasma

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concentrations drop at a rate falling within the scope of the claims wherein there is no degradation of methylphenidate (Pg. 5, 1st paragraph, Pg. 14, Pgs. 18, 19, Examples 4, 5, Figures 3, 4). It is taught that limiting active functionalities, including acidity, of the adhesive monomers is desired to avoid unnecessary degeneration of the methylphenidate and that preferred level of residual monomers is below 2000 ppm (Pgs. 8-10). It is taught that the drug delivery profile is advantageous because the patches are exhausted after use and are not suitable for abuse (Pg. 14). It is taught that the patches are suitable for treatment of ADD and ADHD (Pg. 15).

Miranda et al. teaches that by combining and adjusting the relative proportions acrylic and silicone pressure sensitive adhesives the transdermal permeation rate of drugs, such as methylphenidate, can be adjusted and the adhesive composition advantageously permits selectable loading of the drug (Columns 8, 9, Column 28, line 7).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose a method of treating ADD or ADHD with a methylphenidate patch or the combined use of acrylic and silicone based adhesives. However, the prior art amply suggests the same as it is known that methylphenidate is effective in treating ADD and ADHD and it is known to prepare patches containing methylphenidate. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation that the patches would be effective in treating ADD or ADHD, would provide a drug delivery profile as that claimed in the present invention and prevent degradation of the methylphenidate.

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

Contrary to Applicant's arguments, Examiner does not rely on the statement that the level of residual monomer is below 2000 ppm. Examiner relies on the statement that that limiting active functionalities, including acidity, of the adhesive monomers is desired to avoid unnecessary degeneration of the methylphenidate. More specifically, Vickers discloses that adhesives are preferably essentially neutral and chemically inert (Pg. 8). As such, one of ordinary skill in the art would have been motivated to keep the level of acid functional monomers at a minimum, by optimization of the prior art values as suggested above, including amounts of the acid functional monomers within the claimed amounts.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (703) 308-0067. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Thurman Page, can be reached on (703) 308-2927. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (703) 308-1235 and (703) 308-0198, respectively.

FIC

December 12, 2003



S. MARK CLARDY
PATENT EXAMINER
GROUP 1200
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